K071787

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1) Submitter's name, address, telephone number, contact person:

Beth Bromberg
President
DJA Distributors, LLC
2225 E. Flamingo Road, Suite 204
Las Vegas, Nevada 89119

Phone: (702) 733-9650
Fax: (702) 431-7824

Email:

OCT 26 2007

Date prepared: 13 June 2007

2) Name of the device, including the trade or proprietary name if applicable, the Common or usual name, and the classification name, if known:

Common/Usual Name

BeMitt™ Self Breast Exam

Proprietary Name

BeMitt™ Self Breast Exam

Classification Names

Mammographic X-ray system (892.1710; IZH, regulatory class II)

3) Identification of the predicate or legally marketed device:

DJA Distributors, LLC. believes that the BeMitt™ Self Breast Exam is substantially equivalent to the previously cleared My Breast Friend device from MBF Sales, LLC (Rockville, MD). The predicate 510(k) number is K023390, and Sensa Touch Breast Self Exam Glove from Sante Feminine LTD (Smyrna, Ga). The predicate 510(k) is K042250.

4) Device Description:

The BeMitt™ Self Breast Exam is indicated as an aid for performing breast-self examinations. The device is made of conformable polyurethane and filled with a non-toxic lubricant. While allowing the breast tissue to remain in place during an exam, your fingers can still move effortlessly across the breast while detecting abnormalities.

The BeMitt™ Self Breast Exam is designed to comply with the standards listed below:

Premarket Notification 510(k): Regulatory Requirements for Medical Devices, HHS Publication FDA 95-4158 (1995).

BeMitt™ Self Breast Exam will be cleared and/or approved by the following agency:

U.S. Food and Drug Administration (FDA)

5) Intended Use:

The BeMitt™ Self Breast Exam is indicated as an aid for performing breast-self examinations.

6) Performance Standards:

DJA Distributors, LLC. is not aware of any special controls or performance standards established for this device under sections 513 or 514 of the Food, Drug and Cosmetic Act.

7) Conclusion statements:

In summary, BeMitt™ Self Breast Exam meets or exceeds all safety requirements for a device in its regulatory class and is found to be identical in materials and functionality when compared to the stated predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 26 2007

DJA Distributors, LLC
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K071787
Trade Name: BeMitt™ Breast Self Exam
Regulation Number: 21 CFR 892.1710
Regulation Name: Mammographic x-ray system
Regulatory Class: II
Product Code: IZH
Dated: October 10, 2007
Received: October 11, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K071787

Device Name: BeMitt™ Self Breast Exam

Indications For Use:

The BeMitt™ Self Breast Exam is indicated as an aid for performing breast-self examinations.

Prescription Use _____ AND/OR Over-The Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrency of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K071787